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External hip protectors and risk of hip fracture - Reply

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To the Editor: We have 2 concerns about the study by Ms van Schoor and colleagues.¹ First, many participants were lost to follow-up, potentially creating differences between the intervention and control groups that might have biased the results. Second, many participants assigned to wear the hip protectors stopped doing so during the trial. This dilution of the intervention group with nonusers decreases the power of the study to detect any possible benefit of hip protectors that were actually worn.

These problems could have been addressed by randomizing hips rather than individuals. Each participant would be randomly assigned to wear a single protector on either the right or left side. This design would result in intervention and control hips that would be similar in regard to risk factors for a hip fracture, such as bone strength or propensity for a fall. When participants are lost to follow-up, both of their hips would be lost, retaining the balance of fracture risk factors that was achieved by the initial randomization. The results using this design would be valid to the extent that a hip protector does not affect the side to which a person wearing one might fall.

A matched trial can produce valid risk ratios for all matched pairs by using information only from those pairs that have the study outcome—a hip fracture.²⁻⁵ Therefore most follow-up could be limited to ascertaining information about those who had a fracture. In particular, it would be important to assess whether the participant was wearing the hip protector at the time of the fracture and the side on which the fracture occurred. The data could then be analyzed either according to the initial assignment of each hip to the intervention (which would provide an estimate of effectiveness in the study population), or by an analysis limited to those who were wearing the hip protector when they had a fracture (which would provide an estimate of efficacy when the hip protector is worn). Both analyses would be based on samples of hips that were randomized.

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In Reply: In response to Drs Bulat and Quigley, the evidence available at the time we initiated our study was considered insufficient to establish the effectiveness of external hip protectors, and therefore the use of an usual care control group was approved by the ethical review board of our hospital. Several studies supporting the effectiveness of hip protectors were published while we were collecting data. Most, however, were small or used cluster randomization, which may compromise validity.

Bulat and Quigley are concerned about our use of a calendar to assess falls and fractures, and they raise the possibility that the hip protectors may have lost effectiveness during the 12 months of our trial. The calendar was completed by a nurse when the participant was cognitively impaired. Because this is a prospective method, it is the most reliable method available. According to the manufacturer of the hip protectors, the devices may be used for about 1.5 years. The hip protectors were checked during the unannounced visits, and the nurses contacted us when they believed that the hip protectors should be replaced.

We agree with Dr Honkanen that a 75% risk reduction is ambitious, but at the start of our trial we only had information from a few trials suggesting that this was feasible. Despite this, our study is still the largest randomized controlled trial that uses individual randomization.

Like Bulat and Quigley, Honkanen is concerned about our compliance rate. We have previously reported that compliance rates are low in most studies,¹ and that most studies only report hip fractures in participants who were not compliant. Thus, we cannot exclude poor compliance as a cause for the lack of effectiveness of the hip protector in our study. Hip protectors may be effective when compliance is increased. We agree that future research should focus on interventions to improve compliance and design of the hip protector.

Compliance in our study was assessed by unannounced visits. We believe this to be the most valid method. Other studies did not actually check whether participants were using hip protectors, but relied on diaries or telephone interviews. The diary method may give more complete information, but recall bias and socially desirable answers may occur. In addition to the unannounced visits, we did use the diary method (calendar) and found a trend among participants who fell frequently—those who reported greater compliance had lower fracture rates than those who were less compliant, but this method is less reliable and conclusions should not be drawn from it.

Although type of institution can be an effect modifier in the relationship between the use of hip protectors and hip fractures, in our study this was not the case ($P = .74$ for interaction). Therefore, analyses were not stratified.

We agree with Honkanen that it may be more difficult to get the nursing staff committed to hip protectors when only a few participants per ward are randomized. However, the compliance during our unannounced visits was similar to the com-